Claim 1 is directed to a moisturizing and lubricating composition comprising from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) of an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. No more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature. At least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Krzysik ('075) discloses tissue products comprising a hydrophilic composition for softening the tissue. The composition comprises from about 30 to about 90 weight percent of a hydrophilic solvent, from about 10 to about 50 weight percent of high molecular weight polyethylene glycol, from about 5 to about 40 weight percent of a fatty alcohol (e.g., C_{14}-C_{30}), and from about 0.01 to about 20 weight percent oil soluble/dispersible or lipophilic materials. The composition has a penetration hardness of from about 5 to 360 millimeters and a melting point of from about 30°C to about 70°C.

Significantly, Krzysik fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

As noted in the specification of the present application, liquid components of the moisturizing and lubricating compositions are important in that they provide plasticity and help avoid products that are too hard, brittle, or flaky. However, compositions that contain a high proportion of components that are liquid at room temperature are more difficult to process. Furthermore, if the composition contains too high a proportion of liquid components, the liquid components of the composition may migrate away from the surface of the substrate to which the composition is applied, and into the matrix of the fabric of the substrate. It is thus important that the compositions comprise a certain percentage of components that are solid at room temperature. In particular, the solid components, such as the immobilizing agents, provide a network that is capable of supporting the liquid components within it and, therefore, preventing their migration through the substrate. If the solid portion of the composition is too small, the network may be overwhelmed by the large liquid portion, and the solids portion may be unable to support the liquids in the network. *See* Specification at ¶68. To address this problem, the compositions of the present invention comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature.

There is nothing in Krzysik stating that the compositions disclosed therein should comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature, no recognition of the advantages of such a

composition, and nothing to suggest that the compositions of Krzysik inherently (i.e., necessarily) have such a makeup.

It appears that the Office is assuming that these limitations are inherent in Krzysik. Specifically, with reference to claims 28-30 and 57-59, the Office states that although the prior art does not explicitly recite this property, the prior art will have the same properties since the prior art and the instant claims are the same. Furthermore, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.[1] Applicant asserts, however, that this is an improper assumption.

For example, Krzysik states that the compositions disclosed therein comprise from about 30 to about 90 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. *See* Krzysik at col. 3, ln. 7-9. The compositions of Krzysik may thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Krzysik can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Additionally, Applicant notes that the specific formulations set forth in the Examples of Krzysik either lack entirely one of the components of the composition of claim 1

[1] Office action dated October 24, 2006 at page 5.

and/or comprise amounts of one or more component that falls outside of the claimed ranges. For example, claim 1 requires the composition to comprise from about 1% (by weight) to about 20% (by weight) of a humectant. However, the formulations set forth in Examples 1-8 and 11-15 of Krzysik all comprise more than 20 wt.% humectants. In particular, Applicant notes that glycerin, propylene glycol, and hydrogenated starch hydrolysates may all act as humectants (see Specification, ¶61). However, the total amount of glycerin, propylene glycol, and/or hydrogenated starch hydrolysates exceeds 20 wt.% for all the formulations set forth in Examples 1-8 and 11-15 of Krzysik.[2]

In this regard, Applicant notes that the Office has stated that the compositions of Krzysik may comprise propylene glycol, which is a compatibilizing agent. Therefore, the Office asserts, for example, that the composition of Example 7 comprises 10% propylene glycol, a compatibilizing agent; 10% PEG-400, a compatibilizing agent; 20% PEG-1000 and 30% PEG-8000, immobilizing agents; 10% dimethicone copolyol, an emollient; and 20% hydrogenated starch hydrolysate, a humectant.[3] While it is true that propylene glycol is a suitable compatibilizing agent (*see* Specification, ¶66), propylene glycol, as noted above, is also listed as a suitable humectant (*see* Specification, ¶61). As such, when determining the total amount of humectant in the compositions set forth in the Examples of Krzysik, the amount of propylene glycol in the compositions should also be considered. Thus, the total amount of components in that formulation that act as humectants is 30wt.%, which exceeds the upper end of the

[2] Applicant notes that the formulations set forth in Examples 9 and 10 of Krzysik do not appear to comprise any humectants.
[3] Examples 11-13 have also been cited by the Office as having each and every component, in the required amounts, as the composition of Applicants' claim 1 for the same reasons the Office asserts for Example 7.

range set forth in claim 1 (i.e., about 20% by weight). To further clarify, Applicant is not proposing that propylene glycol acts only as a humectant in the formulations of set forth in Krzysik. As the Office has correctly stated, propylene glycol is a compatibilizing agent, and is in fact listed as a suitable compatibilizing agent in the specification of the present application (*see* specification at paragraph 66). However, as discussed above, the specification of the present application also lists propylene glycol as a suitable humectant for use in the moisturizing and lubrication compositions (see specification at paragraph 61). This dual function of propylene glycol should not be ignored when assessing the amount of humectant in the formulations set forth in Krzysik. Specifically, as propylene glycol may act as both a humectant **and** a compatibilizing agent (as propylene glycol is listed as suitable for both these functions in the specification), the amounts of components in the formulations set forth in Examples of Krzysik that can act as humectants exceeds 20% (by weight), as required in Applicant's claim 1.

Furthermore, Applicant notes that the formulation described in Example 7 of Krzysik has a penetration hardness of approximately 238 millimeters (*see* Krzysik at column 7, line 20). While penetration hardness is not specifically claimed in present claim 1, Applicant does note that the composition of the present application desirably has a penetration hardness of from about 1 millimeter to about 200 millimeters, more desirably from about 1 millimeter to about 120 millimeters, and even more desirably from about 1 millimeter to about 20 millimeters (paragraph 46). Specifically, the softer the compositions (i.e., the higher the penetration hardness number), the more

mobile the compositions will be, making the composition more likely to migrate into the inner layers of an absorbent product or the like. As such, even if the amount of propylene glycol is only considered for the amount of compatibilizing agent (which, as noted above, Applicant asserts that one skilled in the art clearly could not do) and Krzysik discloses each element of claim 1 in the required amounts, the resulting composition will not inherently (i.e., necessarily) have the desired physical properties as desired of the moisturizing and lubricating composition of claim 1; specifically, the composition does not have the desired penetration hardness as the composition of claim 1.

In the Response to Arguments section of the Final Office action, the Office further states that the instant claim language, i.e., "comprising", does not exclude other components in the composition. Thus, the composition is only required to have 1-20% of a humectant, but does not exclude other components such as additional moisturizing agents including hydrogenated starch hydrolysates in the composition. Applicant respectfully disagrees as, while additional ingredients can be included in the composition of Applicant's claim 1[4], the maximum amount of component acting as a humectant is limited to about 20% by weight; that is, the limitation of the composition having from about 1% to about 20% by weight humectant is a positive limitation that cannot be ignored. As such, while additional components can be included within the composition, the amounts required for components that act as humectant are limited to from about 1% to about 20% by weight. Thus, the amount of

[4] Specifically, as claimed in dependent claims 13, 15, 18, 23, and 25, additional components such as dispersing agents, pH modifiers, ceramides, and the like can be included in the composition.

propylene glycol must be considered in the amount of components that act as humectants and the amount of all humectant-type components cannot exceed 20% by weight.

Furthermore, it appears the Office has assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C,"[5] is inherent in Krzysik. This, however, is also an improper assumption.

Krzysik simply states that the compositions disclosed therein have a melting point of from about 30°C to about 70°C. This, however, does not mean that it is inherent that at least about 85% (by weight) of the components of the compositions form a single phase at the composition's melting point. The Krzysik reference defines "melting point" as "the temperature at which the majority of the melting occurs, it being recognized that melting actually occurs over a range of temperatures" (see Krzysik, col. 2, ln. 37-39). The disclosure in Krzysik of the melting point of the compositions thus merely means that the majority of the composition has melted at that temperature; there may, however, still be portions of the composition that have not melted (i.e., solid portions) in the composition, even at the melting temperature.

With regard to Examples 11-13, Applicant submits that no where in any of these Examples is a composition having "at least about 85% (by weight) of the components in a single phase at a temperature of from about 45°C to about 80°C disclosed. Specifically, this limitation of claim 1 requires that at least

[5] As noted in the specification, compatibility of the composition is important for providing a composition that is easily processable and stable (*see* Specification ¶70; *see also* Specification ¶65 for a discussion of the importance of having a compatible composition).

about 85% (by weight) of the components of the composition form a single phase across the entire temperature range (i.e., from about 45°C to about 80°C). The formulations set forth in Examples 11-13 simply do not necessarily meet this limitation.

For instance, the formulation of Example 11 comprises 35wt.% propylene glycol. Propylene glycol is a liquid within the temperature range of 45°C to 80°C. In support of this, we are enclosing Exhibit A, listing the melting point of propylene glycol as -59°C. Thus, the formulation of Example 11 comprises at least 35wt.% components that are liquid within the temperature range of 45°C to 80°C.

Additionally, the formulation of Example 11 comprises 20wt.% polyethylene glycol 8000; 10wt.% behenyl alcohol; and 10wt.% stearyl alcohol, all having melting points that fall within the temperature range of 45°C to about 80°C. In particular, polyethylene glycol 8000 has a melting point of 61°C (Exhibit B); behenyl alcohol has a melting point between 65°C and 73°C (Exhibit C); and stearyl alcohol has a melting point of 61°C (Exhibit D). Since the melting point for all of these components is above 45°C, at least some portion of these components should be solid at the lower end of the 45°C to 80°C temperature range. Thus, in addition to comprising at least 35wt.% components that are liquid within the temperature range of 45°C to 80°C, the formulation of Example 11 also comprises at least around 40wt.% components that are solid at the lower end of the 45°C to 80°C temperature. As such, it cannot be said that at least about 85% (by weight) of the components of the formulation of Example 11 will form a single phase at the composition's melting point. And thus, Krzysik fails to disclose, either explicitly or inherently, compositions wherein

at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

As stated in M.P.E.P. §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since Krzysik fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Krzysik fails to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Krzysik reference.

Claims 2-4, 8-10, 12-13, 15-16, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-4, 8-10, 12-13, 15-16, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and further requires the emollient to be a silicone, and additionally, requires the composition to comprise a dispersing agent. As the Krzysik reference fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 31, Krzysik fails to

disclose each and every limitation of claim 31. As such, claim 31 is novel over the Krzysik reference.

Claims 34-35, 39-41, 43-45, 52-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-35, 39-41, 43-45, 52-54, and 57-59 are patentable for the same reasons as claim 31 set forth above, as well as for the additional elements they require.

2. Rejection of Claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, and 57-59 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, and 57-59 under 35 U.S.C. §102(b) as being anticipated by Tyrell, et al. (U.S. 2002/0120241).

Claim 1 is discussed above.

Tyrell, et al. ('241) disclose skin barrier enhancing compositions that may be used in connection with absorbent articles. The compositions may comprise from about 10 to about 90 weight percent hydrophilic solvents, from about 10 to about 90 weight percent high molecular weight polyethylene glycols, from about 1 to about 40 weight percent fatty alcohols, from about 1 to about 40 weight percent fatty acids, and from about 0.1 to about 20 weight percent anionic (or decoupling) polymers. The compositions may further optionally comprise from about 1 to about 10 weight percent emulsifying surfactants, from about 0.1 to about 30 weight percent natural fats or oils, from about 0.1 to about 10 weight percent sterols, from about 0.1 to about 10 weight percent emollients, from about 1 to about 20 weight percent viscosity enhancers, and/or from about 0.5 to about 10

weight percent rheology modifiers. The compositions have a penetration hardness of from about 5 to about 365 millimeters and a melting point of from about 32°C to about 100°C.

Claim 1 is novel over Tyrell, et al. for similar reasons to those set forth above with respect to the Krzysik reference. More particularly, Tyrell, et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, it cannot be assumed that these limitations are inherent in the compositions of Tyrell, et al. For example, Tyrell, et al. state that the compositions disclosed therein comprise from about 10 to about 90 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. *See* Tyrell, et al. at p. 14, ¶105. The compositions of Tyrell, et al. may thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Tyrell, et al. can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Similar to Krzysik, the Tyrell, et al. reference discloses Examples which either lack entirely one of the components of the composition of claim 1 and/or comprise amounts of one or more

component that falls outside of the claimed ranges. For example, the formulation of Example 13 comprises: 28wt.% propylene glycol (humectant/compatibilizing agent); 5wt.% hydrogenated starch hydrolysate (humectant); 1wt.% chitosan polymer; 25wt.% polyethylene glycol 10,000 (immobilizing agent); 25wt.% behenyl alcohol (emollient/immobilizing agent)[6]; and 10wt.% dimethicone (emollient). As with the formulations of the working Examples in Krzysik discussed above, components such as propylene glycol, which have dual functions (i.e., act as both humectant and compatibilizing agents), must be considered when determining the amounts of both humectant and compatibilizing agent. As such, like in Krzysik, the amount of components that act as humectants is greater than 30wt.%, which exceeds the upper end of the range required in claim 1 (i.e., about 20% by weight).

Furthermore, the formulation of Example 20, which the Office states discloses each and every component of Applicant's formulation, in the claimed amount ranges, comprises 10wt.% propylene glycol (humectant/compatibilizing); 4wt.% polyethylene glycol 200 (compatibilizing agent); 15wt.% polyethylene glycol 10,000 (immobilizing agent); 10wt.% stearyl alcohol (emollient/compatibilizing agent); and 20wt.% dimethicone treated zinc oxide. Applicant asserts that, again, the formulation comprises amounts of one or more component that falls outside of the claimed ranges. Initially, Applicant notes that there is insufficient compatibilizing agent in the formulation. Specifically, the polyethylene glycol 10,000 and stearyl alcohol each act as compatibilizing agent, thereby,

[6] Applicant respectfully notes that behenyl alcohol is used in the formulation of Example 13, not benzyl alcohol as stated by the Office in the Final Office action on page 7.

providing 25wt.% compatibilizing agent in the formulation. Claim 1, however, requires a lower end of about 30% by weight compatibilizing agent. Furthermore, the Office asserts that dimethicone treated zinc oxide is a suitable emollient. While Applicant agrees that dimethicone is a suitable emollient (*see* dependent claim 3), no where in Applicant's present application, nor in the Tyrell, et al. reference, is it taught or suggested that dimethicone treated zinc oxide is suitable as an emollient. As such, no where in Tyrell, et al. is the components, in the amounts required in Applicant's claim 1, taught or suggested.

Furthermore, it cannot be assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C," is inherent in Tyrell, et al. Similar to the Krzysik reference discussed above, simply stating that the compositions disclosed therein have a melting point of from about 45°C to about 80°C, does not mean that it is inherent that at least about 85% (by weight) of the components of the compositions form a single phase at the composition's melting point. Specifically, in the formulation of Example 13 in Tyrell, et al., the formulation comprises 28wt.% propylene glycol. As noted above, propylene glycol is a liquid within the temperature range of 45°C to 80°C. Thus, the formulation of Example 13 comprises at least 28wt.% components that are liquid within the temperature range of 45°C to 80°C.

Additionally, the formulation of Example 13 comprises 25wt.% polyethylene glycol 10,000; and 25wt.% behenyl alcohol, each of which having melting points that fall within or above the temperature range of 45°C to about 80°C. In particular, as noted above, behenyl alcohol has a melting point between 65°C and

73°C (Exhibit C). Further, as known in the art, the melting point of polyethylene glycol increases as the molecular weight increase (e.g., PEG 1500 has a melting point of between 44°C and 48°C; PEG 4000 has a melting point of between 54°C and 58°C; and PEG 6000 has a melting point of between 56°C and 63°C (*see* Exhibit E)), and as such, the melting point of PEG 10,000 is at least within, or even above, the temperature range of 45°C to about 80°C. Since the melting point for both of these components is above 45°C, at least some portion of these components should be solid at the lower end of the 45°C to 80°C temperature range. Thus, in addition to comprising at least 28wt.% components that are liquid within the temperature range of 45°C to 80°C, the formulation of Example 13 also comprises at least around 50wt.% components that are solid at the lower end of the 45°C to 80°C temperature. As such, Tyrell, et al. fail to disclose, either explicitly or inherently, compositions that necessarily have at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

Since Tyrell, et al. fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Tyrell, et al. fail to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Tyrell, et al. reference.

Claims 2-4, 8-10, 12-13, 15-17, 21-22, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-4, 8-10,

12-13, 15-17, 21-22, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and is patentable over the Tyrell, et al. reference for the same reasons as claim 1 set forth above as well as for the additional elements it requires.

Claims 34-35, 39-41, 43-46, 50-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-35, 39-41, 43-46, 50-54, and 57-59 are patentable for the same reasons as claim 31 set forth above, as well as for the additional elements they require.

3. Rejection of Claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, and 57-59 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, and 57-59 under 35 U.S.C. §102(b) as being anticipated by Krzysik, et al. (WO 00/64409).

Claim 1 is discussed above.

Krzysik, et al. ('409) disclose skin barrier enhancing tissue products that comprise a lipid-enriched hydrophilic lotion composition. The composition may comprise from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (having a molecular weight of about 720 or greater), from about 1 to about 30 weight percent of a C_{14} to C_{30} or greater fatty alcohol, from about 0.5 to about 30 weight percent of humectant, from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent sterol or sterol derivative, and from about 0.1 to about 30 weight percent of

natural fats or oils. The compositions have a penetration hardness of from about 5 to about 360 millimeters and a melting point of from about 30°C to about 100°C.

Claim 1 is novel over Krzysik, et al. ('409) for similar reasons to those set forth above with respect to the Krzysik ('075) and Tyrell, et al. references. More particularly, Krzysik et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, it cannot be assumed that these limitations are inherent in the compositions of Krzysik, et al. Similar to Krzysik ('075), Krzysik, et al. ('409) state that the compositions disclosed therein comprise from about 10 to about 95 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. *See* '409 at p. 10, lines 335-337. The compositions of '409 may thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 95 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Krzysik, et al. can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Specifically, similar to Krzysik ('075) and the Tyrell, et al. references, the Krzysik, et al. ('409) reference discloses Examples which either lack entirely one of the components of the composition of claim 1 and/or comprise amounts of one or more component that falls outside of the claimed ranges. For example, Formulas 1-5 set forth in the examples of Krzysik, et al. ('409) (which appear to comprise 88-90% or more water) do not comprise an immobilizing agent in an amount of from about 30% (by weight) to about 90% (by weight), as required by claim 1. Furthermore, Formula 6 comprises: 35wt.% propylene glycol (humectant/compatibilizing agent); 20wt.% polyethylene glycol 8000 (immobilizing agent); 5wt.% glycerin (humectant); 10wt.% behenyl alcohol (emollient/immobilizing agent); 10wt.% stearyl alcohol (emollient/immobilizing agent); and 10wt.% dimethicone (emollient). As with the formulations of the working Examples in Krzysik ('075) and Tyrell, et al. discussed above, components such as propylene glycol, which have dual functions (i.e., act as both humectant and compatibilizing agents), must be considered when determining the amount of both humectant and compatibilizing agent. As such, like in Krzysik ('075) and Tyrell, et al., the amount of components in Formula 6 of Krzysik, et al. ('409) that act as humectants is greater than 50wt.%, which exceeds the upper end of the range set forth in claim 1 (i.e., about 20% by weight).

Furthermore, similar to the analysis of Krzysik ('075) and Tyrell, et al., it cannot be assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C," is inherent in Krzysik, et al. ('409), based on the disclosure in Krzysik, et

al. ('409) of compositions that have melting points that fall within the range of about 45°C to about 80°C. As noted above, Krzysik, et al. ('409) state that the compositions disclosed therein have a melting point of from about 30°C to about 100°C. However, the Krzysik, et al. ('409) reference, like Krzysik ('075) discussed above, defines "melting point" as "the temperature at which the majority of the melting occurs, it being recognized that melting actually occurs over a range of temperatures" (see '409, p. 15, lines 497-499). As such, the disclosure in Krzysik, et al. ('409) of the melting point of the compositions merely means that the majority of the composition has melted at that temperature; there may, however, still be portions of the composition that have not melted (i.e., solid portions) in the composition, even at the melting temperature. Thus, it cannot be assumed that at least about 85% (by weight) of the components of the compositions will form a single phase at the composition's melting point.

More specifically, in Formula 6 there is 35wt.% propylene glycol, which, as noted above, is a liquid within the temperature range of from 45°C to 80°C. Furthermore, as discussed above, Formula 6 comprises 20wt.% PEG 8000; 10wt.% behenyl alcohol; and 10wt.% stearyl alcohol, all of which, as noted above, have a melting point that falls within the temperature range of 45°C to about 80°C. Since the melting point for all of these components is above 45°C, at least some portion of these components should be solid at the lower end of the 45°C to 80°C temperature range. Thus, similar to the formulations in Krzysik ('075) above, in addition to comprising at least 35wt.% components that are liquid within the temperature range of 45°C to 80°C, Formula 6 also comprises at least around 40wt.%

components that are solid at the lower end of the 45°C to 80°C temperature. As such, it cannot be said that at least about 85% (by weight) of the components of Formula 6 form a single phase over the entire temperature range of from a bout 45°C to about 80°C, as required in Applicant's claim 1. The '409 reference thus fails to disclose, either explicitly or inherently, compositions wherein at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

Since Krzysik, et al. ('409) fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Krzysik, et al. fail to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Krzysik, et al. reference.

Claims 2-10, 12-13, 15-22, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-10, 12-13, 15-22, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and is patentable over the Krzysik, et al. reference for the same reasons as claim 1 set forth above as well as for the additional elements it requires.

Claims 34-41, 43-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-41, 43-54, and 57-59 are patentable for the same reasons as claim 31 set forth above, as well as for the additional elements they require.

4. Rejection of Claim 32 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 32 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. ('409).

Claim 32 depends directly on claim 31, which is discussed above. Claim 31 is patentable for the reasons set forth above. In particular, the Krzysik, et al. reference fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some combinations would have been obvious where other would not.[7] The Office has failed to meet its burden under number (1) and/or (2) above, as Krzysik, et al. fail to show each and every limitation of

[7] Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) *See also* KSR Int'l Co. v. Teleflex, Inc., et al. 550 US____, 2007 WL 1237837 at 12 (2007).

Applicant's invention and there is no apparent reason for one skilled in the art to modify Krzysik, et al. to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicant's claimed combinations of components in the moisturizing and lubricating compositions.

As noted above, Krzysik, et al. fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Further, Krzysik, et al. fail to suggest or disclose any reason to one skilled in the art to modify its lipid-enriched hydrophilic lotion composition to comprise a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Specifically, no where in the Krzysik, et al. reference are the advantages of such a composition recognized; that is, no where is the advantage of a composition having adequate amounts of components in the liquid phase over the entire temperature range of 45°C to 80°C, thereby avoiding a product being too hard, brittle, or flaky, nor is the advantage of a composition having adequate amounts of solid components in the temperature range of 45°C to 80°C, so as to keep the composition from migrating away from the surface of the

substrate to which the composition is applied, recognized and/or desired.

As such, the Krzysik, et al. reference fails to provide a reason why one skilled in the art would choose to use components in their compositions that would provide for no more than about 50% (by weight) of the components being liquid at room temperature and no less than about 50% of the components being solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Specifically, no where is there motivation or suggestion for such a combination of components. Furthermore, as noted above, the Krzysik et al. reference teaches the preferred hydrophilic solvent, which makes up 10% to 95% by weight of their compositions, to be low molecular weight polyethylene glycols having molecular weights of less than 720 and being liquids at room temperature. As such, one skilled in the art would not, and could not, be motivated to look to the components of the compositions of the Krzysik, et al. reference to arrive at the compositions of Applicant's claim 31.

There is simply no reason to modify the Krzysik, et al. reference to arrive at claim 31, and claim 32, which depends on claim 31, cannot be said to be obvious in view of the cited reference.

5. Rejection of Claims 23-24 and 55-56 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 23-24 and 55-56 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. in view of Elias, et al. (U.S. 5,643,899).

Claims 23-24 and 55-56 depend from claims 1 and 31, respectively. As such, claims 23-24 and 55-56 are patentable over Krzysik, et al. for the same reasons as claims 1 and 31 set forth above. Specifically, Krzysik, et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Elias, et al. fail to overcome the above shortcoming. Specifically, Elias, et al. disclose topical formulations for repairing the epidermal barrier function. Specifically, the formulations contain various combinations of lipids selected from the three major epidermal lipid classes (i.e., ceramides, cholesterol, and free fatty acids) or their structurally similar precursors, isomers, or analogs.[8] Specifically preferred embodiments of the lipid formulations include: (1) a two-component combination of cholesterol and acylceramide; (2) a three-component combination of cholesterol, acylceramide, and one or more fatty acids of 12-20 carbon atom length; (3) four-component combination of cholesterol, ceramide, essential fatty acid, and non-essential or bulk fatty acids of 12-20 carbon atom lengths; (4) combinations of (1) and (2) with the acylceramide replaced by a glycoceramide; (5) combinations of (1), (2), (3), or (4) with petrolatum, glycerin, or both added; and (6) a glycoceramide or acylglycoceramide with trehalose as the glyco moiety.[9]

Significantly, no where in Elias, et al. is it disclosed to

[8] *See* Elias et al. at col. 1, ln. 50-54 and col.4, ln. 53-56.

use a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. As such, claims 23-24 and 55-56 are patentable over Krzysik, et al. in view of Elias, et al.

6. Rejection of Claims 14 and 33 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 14 and 33 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. in view of Mitchnick, et al. (U.S. 6,103,267).

Claims 14 and 33 depend from claims 1 and 31, respectively. As such, claims 14 and 33 are patentable over Krzysik, et al. for the same reasons as claims 1 and 31 set forth above. Specifically, Krzysik, et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Mitchnick, et al. fail to overcome the above shortcoming. Specifically, Mitchnick, et al. disclose a non-aqueous dispersion of hydrophilic particles that contain stabilized ascorbic acid, which is useful in the cosmetic, dermatological and/or veterinary fields. Specifically, in one embodiment, the dispersion comprises a non-aqueous phase containing particles

[9] *Id.* at col. 5, ln. 18-55.

comprising a water-soluble polymer, such as vitamins, anti-inflammatory agents, anesthetics, analgesics, enzymes, etc.[10], ascorbic acid, and water (e.g., aqueous phase). The particles of the dispersion have a number average diameter of less than 2 microns. The dispersion of Mitchnick, et al. can further comprise a surface active agent for stabilizing the dispersion. Specifically, in one particularly preferred embodiment, the dispersion is a water-in-silicone dispersion comprising from about 0.1% to about 10% surface active agent for dispersing the discontinuous phase into the continuous silicone phase.

Significantly, no where in Mitchnick, et al. is it disclosed that the dispersion comprises no more than about 50% (by weight) components being liquid at room temperature and no less than about 50% components being solid at room temperature, and wherein at least about 85% (by weight) of the components of the dispersion form a single phase at a temperature of from about 45°C to about 80°C. As such, claims 23-24 and 55-56 are patentable over Krzysik, et al. in view of Mitchnick, et al.

7. Rejection of Claims 1-59 for Obviousness Type Double Patenting

Claims 1-59 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 and 32-60 of co-pending U.S. Patent Application No. 10/659,969 and claims 1-59 of co-pending U.S. Patent Application No. 10/659,862.

Applicants respectfully call the Office's attention to MPEP §804, I.B.1., which notes that if "provisional" obviousness-type double patenting rejections in two or more applications are the

[10] *See* Mitchnick et al. at col. 3, ln. 37-44 and col. 4, ln. 37-39.

only rejections remaining in those applications and all applications are filed on the same day, the examiner should determine which application claims the base invention and which application(s) claims the improvement (added limitations). The obviousness-type double patenting rejection in the base application can be withdrawn without a terminal disclaimer, while the obviousness-type double patenting rejection in the improvement application(s) cannot be withdrawn without a terminal disclaimer. The present application and co-pending Application Nos. 10/659,969 and 10/659,862 were all filed on September 11, 2003. As this provisional rejection is not the only rejection in the present application, Applicants would like to delay responding to this rejection. If the Office has any questions please contact Mr. Christopher M. Goff at 314-231-5400.

Even if upon entry of this Letter To Patent And Trademark Office After Final Office Action, the 102(b) and 103(a) rejections are overcome (which Applicants believe that they have) and the provisional obviousness-type double patenting rejection is the only rejection remaining in the present application, the present rejection is premature. As stated in MPEP §804, I.B.1., since it is not evident which of the pending applications the Office would determine to be the "base application," any action with regard to the present rejection is premature, until such a determination has been made.

8. Rejection of Claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 for Obviousness-type Double Patenting over U.S. Patent No. 5,869,075

Reconsideration is requested of the rejection of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 under the judicially created doctrine of obviousness-type double patenting in view of claims 16-33 of U.S. Patent No. 5,869,075 ('075). In particular, the Office has stated that the claims of the instant application are not patentably distinct from the claims of '075 because while '075 does not claim the instant composition having the specific combination of from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) of an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, independent claim 16 (of '075), and its dependent claims, claim similar components, and therefore, similar subject matter.

Applicants respectfully submit that the subject matter of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the instant application would not have been obvious in view of claims 16-33 of '075. The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. §103 obviousness determination.

In the instant case, the Office appears to state that the composition as claimed in claims 16-33 of '075 comprise the same or a slight variation of the composition of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the present application, and as such, similar compositions and therapeutic results by the instantly claimed compositions of the present invention would have been expected by those of ordinary skill. This, however, is clearly not the case.

As noted above, by requiring the presently claimed moisturizing and lubricating composition to include no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature, the composition provides sufficient plasticity to help avoid products that are too hard, brittle, or flaky, while preventing the components of the composition from migrating away from the surface of a substrate to which the composition is applied. Nothing in claims 16-33 of '075 state that their composition should comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature. More importantly, there is no recognition in the claims of '075 or otherwise of the advantages of such a composition, and nothing to suggest that the compositions of '075 would inherently have such a makeup.

Furthermore, as claimed in claim 17 of '075, the hydrophilic solvents can include 30% (by weight) to about 90% (by weight) low molecular weight polyethylene glycol, and as noted above, as defined in '075, low molecular weight polyethylene glycols are liquid at room temperature. As such, the compositions as claimed in '075 may comprise more than 50%

(by weight) of components that are liquid at room temperature (i.e., may comprise up to 90% (by weight) low molecular weight polyethylene glycols, which are liquid at room temperature). Moreover, the Office has offered no convincing line of reasoning as to why a person of ordinary skill in the art would conclude that the compositions as claimed in '075 would require no more than about 50% (by weight) of components that are liquid at room temperature.

In the Response to Arguments section of the Final Office action, the Office points to dependent claims 23 and 29-30 as being directed to compositions having the claimed combination of components and amounts. Applicants respectfully disagree, as noted above, propylene glycol, which is required in each of dependent claims 23 and 29-30, acts as both a humectant and a compatibilizing agent and, as such, the amount of propylene glycol must be taken into consideration when determining the amount of humectant. As such, as seen in the working Examples discussed above for the '075 reference, the compositions of claims 23 and 29-30 contain humectant in amounts that exceed Applicant's required amount of claim 1 (i.e., from about 1% to a bout 20% by weight).

As such, the moisturizing and lubricating compositions of the present application are patentably distinct from the compositions claimed in '075. Applicants thus respectfully submit that the nonstatutory obviousness-type double patenting rejection over U.S. Patent No. '075 is improper, and request withdrawal of this rejection.

9. Rejection of Claims 1, 4-10, 13, 15-17, 21-22, and 25-30 for Obviousness-type Double Patenting over U.S. Patent No. 6,475,197

Reconsideration is requested of the rejection of claims 1, 4-10, 13, 15-17, 21-22, and 25-30 under the judicially created doctrine of obviousness-type double patenting in view of claims 1-43 of U.S. Patent No. 6,475,197 ('197). In particular, the Office has stated that the claims of the instant application are not patentably distinct from the claims of '197 because although the instant claims are directed to a composition and the claims of '197 are directed to absorbent products, the claims are obvious over each other since the absorbent product of '197 could comprise the instantly claimed moisturizing and lubricating composition.

Applicants respectfully submit that the subject matter of claims 1, 4-10, 13, 15-17, 21-22, and 25-30 of the instant application would not have been obvious in view of claims 1-43 of '197.

Specifically, '197 claims a body facing material having an outer surface, wherein the outer surface of the body facing material has a composition that enhances skin barrier. The composition consists of: from about 10 to about 90 weight percent hydrophilic solvent; from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater; from about 1 to about 30 weight percent of a C_{14} to C_{30} or greater fatty alcohol; from about 0.5 to about 10 weight percent of humectant; from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7; from about 0.1 to

about 20 weight percent of sterol or sterol derivative; and from about 0.1 to about 30 weight percent of natural fats or oils.

In the instant case, the Office appears to state that the absorbent products as claimed in claims 1-43 of '197 comprise the same or a slight variation of the composition of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the present application, and as such, similar compositions and therapeutic products incorporating the instantly claimed compositions of the present invention would have been expected by those of ordinary skill. This, however, is clearly not the case.

As noted above, by requiring the presently claimed moisturizing and lubricating composition to include no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature, the composition provides sufficient plasticity to help avoid products that are too hard, brittle, or flaky, while preventing the components of the composition from migrating away from the surface of a substrate to which the composition is applied. Nothing in claims 1-43 of '197 state that their absorbent products should comprise a composition having no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature. More importantly, there is no recognition in the claims of '197 or otherwise of the advantages of using such a composition, and nothing to suggest that the compositions used in the absorbent products of '197 would inherently have such a makeup.

Furthermore, as claimed in claim 1 of '197, the compositions can include 10% (by weight) to about 90% (by weight) hydrophilic solvents. One particularly preferred

hydrophilic solvent is a low molecular weight polyethylene glycol, and as defined in '197, low molecular weight polyethylene glycols are liquid at room temperature. As such, the compositions used in the articles as claimed in '197 may comprise more than 50% (by weight) of components that are liquid at room temperature (i.e., may comprise up to 90% (by weight) low molecular weight polyethylene glycols, which are liquid at room temperature). Moreover, the Office has offered no convincing line of reasoning as to why a person of ordinary skill in the art would conclude that the compositions as claimed in '197 would require the composition to include no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature.

Moreover, in dependent claim 8 of '197, the composition requires the hydrophilic solvent, which, as noted above, is present in the composition in an amount of from about 10 weight percent to about 90 weight percent, to be propylene glycol. As noted above, propylene glycol acts as a humectant. As such, the composition claimed in '197 can comprise an amount of humectant that exceeds that required in the instant claim 1, specifically, the composition of '197 may contain 90 weight percent humectant. As the compositions of '197 do not contain the same components, in the amounts required in Applicant's claim 1, it cannot be said that the properties of the composition (e.g., that no more than 50% of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature and wherein at least about 85% of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C) would be obvious.

As such, the moisturizing and lubricating compositions of the present application are patentably distinct from the compositions used in the absorbent products as claimed in '197. Applicant thus respectfully submits that the nonstatutory obviousness-type double patenting rejection over U.S. Patent No. '197 is improper, and request withdrawal of this rejection.

In view of the above, Applicant respectfully requests favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fees in connection with this Letter To Patent And Trademark Office After Final Office Action to Deposit Account Number 19-1345 in the name of Senniger Powers.

Respectfully submitted,

/Christopher M. Goff/

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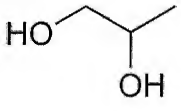
St. Louis, Missouri 63102
(314) 231-5400

CMG/JMB/dhm

Via EFS

Propylene glycol

From Wikipedia, the free encyclopedia

Propylene glycol	
	
Systematic name	propane-1,2-diol
Other names	propylene glycol
Chemical formula	$C_3H_8O_2$
Molecular mass	76.09 g/mol
Density	1.036 g/cm^3
Melting point	-59 °C
Boiling point	188.2 °C
Thermal Conductivity	0.34 W/m-K (50% H2O @ 90°C)
CAS number	[57-55-6]
SMILES	CC(O)CO
Disclaimer and references	

Propylene glycol, known also by the systematic name propane-1,2-diol, is an organic compound (a diol alcohol), usually a tasteless, odorless, and colorless clear oily liquid that is hygroscopic and miscible with water, acetone, and chloroform. It is manufactured

by the hydration of propylene oxide. It can also be converted from glycerol, a biodiesel byproduct.

Contents

Applications

Propylene glycol is used:

- As a moisturizer in medicines, cosmetics, food, toothpaste, and tobacco products
- As a medical and sexual lubricant (A.K.A. "personal lubricant")
- As an emulsification agent in Angostura and Orange bitters
- As a solvent for food colors and flavourings
- As a humectant food additive, labeled as E number E1520
- As a carrier in fragrance oils
- As a non-toxic antifreeze
- In smoke machines to make artificial smoke for use in firefighters' training and theatrical productions
- In hand sanitizers, antibacterial lotions, and saline solutions
- As a main ingredient in many cosmetic products, including baby wipes, bubble baths, deodorants, shampoos, and hair dyes
- As a base ingredient in aircraft deicing fluid and some automobile antifreezes
- In cryonics
- As a working fluid in hydraulic presses
- To regulate humidity in a cigar humidor
- As the killing and preserving agent in pitfall traps, usually used to capture ground beetles
- To treat livestock ketosis

Safety

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act. 21CFR589.1001

The Food and Drug Administration (FDA) has determined propylene glycol to be "generally recognized as safe" for use in food, cosmetics, and medicines. Like ethylene glycol, propylene glycol affects the body's chemistry by increasing the amount of acid. Propylene glycol is metabolized into lactic acid, which occurs naturally as muscles are exercised, while ethylene glycol is metabolized into oxalic acid, which is toxic.

Post menopausal women who require the use of an estrogen cream may notice that brand name creams made with propylene glycol often create extreme, uncomfortable burning along the vulva and perianal area. In these cases, patients can request that a local compounding pharmacy make a "propylene glycol free" cream which, not surprisingly, is much more tolerable.

Patients with vulvodynia and interstitial cystitis may be especially sensitive to propylene glycol. Women struggling with yeast infections may also notice that some OTC creams can cause intense burning.[1]

Notes

1. ^ Elizabeth Vliet MD, Screaming To Be Heard: Hormonal Connections That Women Suspect and Doctors Ignore". M. Evans and Company, Inc. New York 1995

Reference

- *Merck Index*, 11th Edition, **7868**

See Also

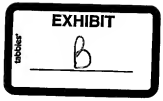
- Ethylene glycol

External link

- ATSDR ToxFAQs™ for Ethylene Glycol and Propylene Glycol
- Propylene Glycol info at DOW Chemical
- Propylene Glycol info at Scorecard.com

- Links to external chemical sources

Categories: Polyols | Household chemicals | Solvents | Cosmetic chemicals | Food additives



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Print Product Info Email Product Info Request a Sample

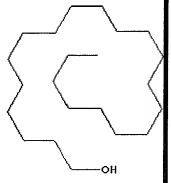
Product:	Polyethylene Glycol 8000, NF FCC
CAS:	25322-68-3
Synonym:	PEG 8000
Formula:	HO(CH2CH20)nH
Class:	Plasticizers - Esters - Surfactants

SPECIFICATIONS	
Sensorlc	White Flakes
pH	4.5-7.5
Viscocity	470-900
Soluble	Slightly hazy
Flash Point COC °C	269
Color, APHA; ASTM D 1209	25 max
Average Molecular Weight	7000-9000
Melting Point	61°C
Specific Gravity (20°C/4°C)	1.22

Notes
PEG 8000 is the addition polymer of ethylene oxide which has an average molecular weight of 8000. Product description and applications: Argriculture, Chemical Intermediates, Cosmetics, Industrial Cleaners, Metal Processing, Pharmaceuticals, Rubber Processing, Ceramics, Coatings, Adhesives, Household cleaners, Lubricants, paints, polishes, and textiles Packaging: 61 gal. non-returnable drum, 250 lbs. Regulatory Information: PEG 8000 is suitable for use as an inderect food additive Storage: PEG 800 should be stored in closed, factory sealed containers at temperatures not exceeding 32°C. Product stored for a prolonged period of time should be kept under a nitrogen atmosphere. Product should be used within one year of delivery.

EXHIBIT
bobbie
C

BEHENYL ALCOHOL



PRODUCT IDENTIFICATION

CAS NO.	661-19-8
EINECS NO.	211-546-6
FORMULA	$CH_3(CH_2)_{20}CH_2OH$
MOL WT.	326.60
H.S. CODE	2905.29
TOXICITY	Oral rat LD50: 12800 mg/kg
SYNONYMS	1-Docosanol; docosan-1-ol; Behenic alcohol; Docosyl alcohol; Docosanol-(1); n-Eicosanol;
DERIVATION	
CLASSIFICATION	

PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	white solid
MELTING POINT	65 - 73 C
BOILING POINT	180 C at 0.22 mm Hg
SPECIFIC GRAVITY	
SOLUBILITY IN WATER	Insoluble
pH	
VAPOR DENSITY	
AUTOIGNITION	
NFPA RATINGS	Health: 1; Flammability: 0; Reactivity: 0
REFRACTIVE INDEX	
FLASH POINT	
STABILITY	Stable under ordinary conditions

GENERAL DESCRIPTION AND APPLICATIONS

Fatty alcohols, derived from natural fats and oils, are high molecular straight chain primary alcohols. They include lauryl (C12), Myristyl (C14), Cetyl (or palmityl: C16), stearyl (C18), Oleyl (C18, unsaturated), and Linoleyl (C18, polyunsaturated) alcohols. There are synthetic fatty alcohols equivalent physically and chemically to natural alcohols obtained from oleochemical sources such as coconut and palm kernel oil. Fatty alcohols are emulsifiers and emollients to make skin smoother and prevent moisture loss. Identical fatty esters are used to improve rub-out of formulas and to control viscosity and dispersion characteristics in cosmetics, personal care products and pharmaceutical ingredients. As chemical intermediates, the primary use of fatty alcohols are as raw material for the production of fatty sulfate salts and alcohol ethoxylates for foaming and cleaning purposes in the field of detergent industry. Chemical reactions of primary alcohols include esterifications, ethoxylation, sulfation, oxidation and many other reactions. Their derivatives and end use applications include;

- Nonionic surfactants (Ethoxylates and propoxylates)
- Anionic surfactants (Alkyl sulfates and alkyl ethoxy sulfates)
- Chemical intermediates and polymerization modifiers (Alkyl halides, Alkyl mercaptans)
- Quaternary ammonium compounds for detergent sanitisers, softner for textiles, phase transfer catalyst and biocides
- Antioxidants for plastics (Alkyl thiopropionates and alkyl phosphites)
- Lubricant additives (Metallic and thio alkylphosphates)

- Flavor and Fragrance (Aldehydes and ketones)
- PVC plasticizers (Dialkyl Phthalates, adipates and trimellitates)
- Coatings and inks (acrylate and methacrylate esters)
- Water treatment (acrylate and methacrylate esters)

Large amount of fatty alcohols are used as special solvents, fillers in plasticizer and insulating materials for the building industry. Fatty alcohols are used as ingredients in the industries of agricultural, foodstuff, metal processing, cosmetics, lube additive, pharmaceutical, rubber, textile, perfume and flavouring as well as synthetic detergent.

In pharmaceutical application, behenyl alcohol (a saturated 22-carbon alcohol) exhibits antiviral activity against lipid-enveloped viruses including herpes simplex virus (HSV). Behenyl alcohol is used as an ingredient in the cream for topical treatment of recurrent herpes. It acts by inhibiting fusion between the human plasma cell membrane and the viral envelope.

LSALES SPECIFICATION

APPEARANCE	white solid
ASSAY	78.0 - 85.0% (C22 Alcohol)
ACID VALUE	0.2 max (mg KOH/g)
IODINE VALUE	1.0 max (mg KOH/g)
SAP VALUE	1.0 max (mg KOH/g)
COLOR, APHA	100 max
TRANSPORTATION	
PACKING	25kgs in bag
HAZARD CLASS	Not regulated
UN NO.	

OTHER INFORMATION

European Hazard Symbols: , Risk Phrases: , Safety Phrases: 22-45/46

GENERAL DESCRIPTION OF FATTY ACID

Fatty Acids are aliphatic carboxylic acid with varying hydrocarbon lengths at one end of the chain joined to terminal carboxyl (-COOH) group at the other end. The general formula is R-$(CH_2)_n$-COOH. Fatty acids are predominantly unbranched and those with even numbers of carbon atoms between 12 and 22 carbons long react with glycerol to form lipids (fat-soluble components of living cells) in plants, animals, and microorganisms. Fatty acids all have common names respectively like lauric (C12), Myristic (C14), palmitic (C16), stearic (C18), oleic (C18, unsaturated), and linoleic (C18, polyunsaturated) acids. The saturated fatty acids have no double bonds, while oleic acid is an unsaturated fatty acid has one double bond (also described as olefinic) and polyunsaturated fatty acids like linolenic acid contain two or more double bonds. Lauric acid (also called Dodecanoic acid) is the main acid in coconut oil (45 - 50 percent) and palm kernel oil (45 - 55 percent). Nutmeg butter is rich in myristic acid (also called Tetradecanoic acid) which constitutes 60-75 percent of the fatty-acid content. Palmitic acid(also called Hexadecylic acid) constitutes between 20 and 30 percent of most animal fats and is also an important constituent of most vegetable fats (35 - 45 percent of palm oil). Stearic acid (also called Octadecanoic Acid) is nature's most common long-chain fatty acids, derived from animal and vegetable fats. It is widely used as a lubricant and as an additive in industrial preparations. It is used in the manufacture of metallic stearates, pharmaceuticals, soaps, cosmetics, and food packaging. It is also used as a softener, accelerator activator and dispersing agent in rubbers. Oleic acid (systematic chemical name is cis-octadec-9-enoic acid) is the most abundant of the unsaturated fatty acids in nature.

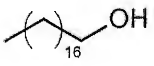
- SATURATED FATTY ACIDS

MELTING

COMMON NAME	SYSTEMATIC NAME	CAS RN	Length	POINT
Undecylic Acid	n-Hendecanoic Acid	112-37-8	Straight 11:0	30 C
Lauric Acid	n-Dodecanoic Acid	143-07-7	Straight 12:0	44 C
Tridecylic Acid	n-Tridecanoic Acid	638-53-9	Straight 13:0	42 C
Myristic Acid	n-Tetradecanoic Acid	544-63-8	Straight 14:0	54 C
Pentadecanoic Acid	n-Pentadecanoic Acid	1002-84-2	Straight 15:0	52 C
Palmitic Acid	n-Hexadecanoic Acid	57-10-3	Straight 16:0	62 C
Margaric Acid	n-Heptadecanoic Acid	506-12-7	Straight 17:0	61 C
Stearic Acid	n-Octadecanoic Acid	57-11-4	Straight 18:0	70 C
Nondecylic Acid	n-Nonadecanoic Acid	646-30-0	Straight 19:0	70 C
Arachidic Acid	n-Eicosanoic Acid	506-30-9	Straight 20:0	75 C
Henicosanoic acid	n-Heneicosanoic Acid	2363-71-5	Straight 21:0	74 C
Behenic Acid	n-Docosanoic Acid	112-85-6	Straight 22:0	81 C
Tricosanoic acid	n-Tricosanoic acid	2433-96-7	Straight 23:0	80 C
Lignoceric Acid	n-Tetracosanoic Acid	557-59-5	Straight 24:0	85 C
Pentacosanoic Acid	n-Pentacosanoic Acid	506-38-7	Straight 25:0	85 C
Cerotinic acid	n-Hexacosanoic acid	506-46-7	Straight 26:0	87 C
Heptacosanoic Acid	n-Heptacosanoic Acid	7138-40-1	Straight 27:0	87 C
Montanic acid	n-Octacosanoic acid	506-48-9	Straight 28:0	91 C
Nonacosanoic Acid	n-Nonacosanoic Acid	4250-38-8	Straight 29:0	91 C
Melissic acid	n-Triacontanoic acid	506-50-3	Straight 30:0	93 C
	n-Hentriacontanoic Acid	38232-01-8	Straight 31:0	
Lacceroic Acid	n-Dotriacontanoic Acid		Straight 32:0	
Ceromelissic Acid	n-Tritriacontanoic acid		Straight 33:0	
Geddic Acid	n-Tetratriacontanoic acid		Straight 34:0	
Ceroplastic Acid	n-Pentatriacontanoic acid		Straight 35:0	

Stearyl alcohol

From Wikipedia, the free encyclopedia

Stearyl alcohol	
	
IUPAC name	1-Octadecanol
Other names	Octadecyl alchohol, stearyl alcohol
Identifiers	
CAS number	[112-92-5]
SMILES	CCCCCCCCCCCCCCCCCO
Properties	
Molecular formula	$CH_3(CH_2)_{17}OH$
Molar mass	270.49 g/mol
Density	0.812 g/cm³
Melting point	61 °C, 334 K, 142 °F
Boiling point	336 °C, 609 K, 637 °F
Except where noted otherwise, data are given for materials in their standard state	

(at 25 °C, 100 kPa) Infobox disclaimer and references

Stearyl alcohol (also known as *octadecyl alcohol* or *1-octadecanol*) is a substance prepared from stearic acid by the process of catalytic hydrogenation. It is a fatty alcohol. It takes the form of white solid granules or flakes which are insoluble in water, with a melting point of 59°C and boiling point of 210°C. It has a wide range of uses as an ingredient in lubricants, resins, perfumes and cosmetics. It is used as an emollient, emulsifier, and thickener in ointments of various sorts, and is widely used as a hair coating in shampoos and hair conditioners.

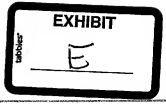
Its chemical formula is $CH_3(CH_2)_{17}OH$.

External links

- Links to external chemical sources

This article about an alcohol is a stub. You can help Wikipedia by expanding it.

Categories: Fatty alcohols | Surfactants | Alcohol stubs



MSDS Number: **P5029** * * * * * *Effective Date: **01/09/06** * * * * * Supercedes: **08/10/04***

MSDS Material Safety Data Sheet

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

Mallinckrodt CHEMICALS

J.T.Baker

24 Hour Emergency Telephone: 908-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

POLYETHYLENE GLYCOL

1. Product Identification

Synonyms: PEG; Carbowax®; Polyglycol; Polyethylene glycol 200, 300, 400, 600,1000,1450, 3350, 4000, 6000, 8000 and 20000.
CAS No.: 25322-68-3
Molecular Weight: Not applicable to mixtures.
Chemical Formula: (C2H4O) n.H2O
Product Codes:
J.T. Baker: U204, U214, U215, U216, U218, U220, U221, U222
Mallinckrodt: 7755, H273

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Polyethylene Glycol	25322-68-3	90 - 100%	No

3. Hazards Identification

Emergency Overview

As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance and ensure prompt removal from skin, eyes and clothing.

SAF-T-DATA$^{(tm)}$ Ratings (Provided here for your convenience)

Health Rating: 1 - Slight
Flammability Rating: 1 - Slight
Reactivity Rating: 1 - Slight
Contact Rating: 0 - None
Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES
Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:
No adverse health effects expected from inhalation. (May be a mechanical irritant.)
Ingestion:
Large doses of the lower molecular weight products may cause gastro-intestinal upset.
Skin Contact:
No adverse effects expected.
Eye Contact:
No adverse effects expected.
Chronic Exposure:
No information found.
Aggravation of Pre-existing Conditions:
Damaged skin.

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4. First Aid Measures

Inhalation:
Not expected to require first aid measures.
Ingestion:

If large amounts were swallowed, give water to drink and get medical advice.

Skin Contact:
In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops or persists.

Eye Contact:
In case of contact, flush eyes with plenty of water for at least 15 minutes. Get medical advice if irritation develops.

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5. Fire Fighting Measures

Fire:
As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. (increases as molecular weight increases).
Flash point: 182 - 287 C.

Explosion:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Fire Extinguishing Media:
Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

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6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8.

Solid Spills: Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container.

Liquid Spills: Absorb with vermiculite, dry sand, earth or similar material and place in a chemical waste container. Do not use combustible materials, such as saw dust. Do not flush to sewer.

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7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues (dust, solids, vapors, liquid); observe all warnings and precautions listed for the product.

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8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
AIHA Workplace Environmental Exposure Level (WEEL):
Polypropylene glycols: 8-hour TWA: 10 mg/m3, as an aerosol

Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
For use with solids (not required for liquids): If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

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9. Physical and Chemical Properties

Appearance:
Clear liquid or white solid.
Odor:
Mild odor.
Solubility:
Soluble in water.
Density:
range: 1.1 to 1.2 (increases as molecular weight increases)
pH:
No information found.
% Volatiles by volume @ 21C (70F):
No information found.
Boiling Point:
No information found.
Melting Point:
Melting point increases as molecular weight increases: PEG 400 = 4-8C (39-46F) PEG 600 = 20-25C (68-77F) PEG1500 = 44-48C (111-118F) PEG 4000 = 54-58C (129-136F) PEG 6000 = 56-63C (133-145F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
Vapor pressure is very low; as molecular weight increases, vapor pressure decreases.
Evaporation Rate (BuAc=1):
No information found.

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10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
Carbon dioxide and carbon monoxide may form when heated to decomposition.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Incompatible with polymerization catalysts (peroxides, persulfates) and accelerators, strong oxidizers, strong bases and strong acids.
Conditions to Avoid:
Incompatibles.

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11. Toxicological Information

Oral Rat LD50 for:
PEG 200 = 28gm/kg; PEG 300 = 27.5gm/kg; PEG 400 = 30.2gm/kg; PEG 600 = 30gm/kg; PEG 1000 = 32gm/kg; PEG 1450 = > 4gm/kg; PEG 4000 = 50gm/kg; PEG 6000 = > 50gm/kg; PEG 20000 = 31.6gm/kg
Polyethylene glycol has been investigated as a mutagen; PEG 1000 has been investigated as a tumorigen.

--------\Cancer Lists\----------

Ingredient	---NTP Carcinogen--- Known	Anticipated	IARC Category
Polyethylene Glycol (25322-68-3)	No	No	None

12. Ecological Information

Environmental Fate:
No information found.
Environmental Toxicity:
No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\------------------------
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Ingredient	TSCA	EC	Japan	Australia
Polyethylene Glycol (25322-68-3)	Yes	No	Yes	Yes

--------\Chemical Inventory Status - Part 2\------------------------
----

Ingredient	Korea	Canada-- DSL	NDSL	Phil.
Polyethylene Glycol (25322-68-3)	Yes	Yes	No	Yes

--------\Federal, State & International Regulations - Part 1\--------
----

Ingredient	RQ	-SARA 302- TPQ	List	------SARA 313------ Chemical Catg.
Polyethylene Glycol (25322-68-3)	No	No	No	No

--------\Federal, State & International Regulations - Part 2\--------
----

Ingredient	CERCLA	-RCRA- 261.33	8(d)	TSCA-
Polyethylene Glycol (25322-68-3)	No	No	No	-

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: No Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **0** Flammability: **1** Reactivity: **0**
Label Hazard Warning:
As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance and ensure prompt removal from skin, eyes and clothing.
Label Precautions:
None.
Label First Aid:
Not applicable.
Product Use:
Laboratory Reagent.
Revision Information:
MSDS Section(s) changed since last revision of document include: 3.
Disclaimer:
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